REMARKS/ARGUMENTS

Reconsideration of this application as amended is respectfully requested. Claim 83 has been amended, claim 88 was previously cancelled and claim 100 has been newly inserted. Therefore, claims 83-87 and 89-100 are in this application. Claims 91-99 have been withdrawn from further consideration. Accordingly, claims 83-87, 89-90 and 100 are now presented for the Examiner's consideration in view of the following comments.

It is respectfully submitted that good cause has been demonstrated for the entry of the present amendment, not only since it overcomes the Examiner's rejections as set forth in the Official Action, thus clearly reducing the number of issues for purposes of appeal, but since the present response places all of the remaining claims in condition for immediate allowance, as will be more clearly demonstrated below.

Initially, applicants have made several amendments to the specification in order to correct manifest typographical errors therein. Entry of these amendments is respectfully requested. No new matter has been added.

In the Official Action, claims 83-87 and 89-90 were rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,234,447 to Kaster et al. ("*Kaster*") in view of U.S. Patent No. 6,206,913 to Yencho et al. ("*Yencho*"). Applicants respectfully traverse this rejection.

Applicants would initially direct the Examiner's attention to the requirement in claim 83 for

> "a plurality of first members...being *resiliently biased* to extend substantially radially out from the structure and being *elastically deflectable* to an orientation substantially parallel to a central longitudinal axis of the structure." (emphasis added)

Applicants submit that neither *Kaster* nor *Yencho* teaches or suggests this feature.

Turning first to *Kaster*, applicants note that the reference teaches a surgical staple formed from stainless steel. (col. 5, lns. 54-55.) Such material exhibits plastic behavior, not elastic behavior. That is, the material will deform under the application of a load or stress, and will retain its deformed configuration once that load has been removed, whereas elastic materials will return to their original shape once the load has been removed. Consider the difference between a block of modeling clay (plastic) and an ordinary kitchen sponge (elastic). When you push down on the modeling clay, it will deform into a new shape and stay there when the pushing force has been removed. On the other hand, when you push down on a kitchen sponge, it will deform into a new shape, but when the pushing force is removed, the sponge will return to its original shape. That the surgical staple of *Kaster* exhibits plastic behavior is clear from the description of the manufacture and use of the staple. Thus, the staple is converted from the flat configuration of Fig. 8 to a curved or annular configuration of Fig. 10 by deforming the staple around a mandrel, whereupon it retains the annular configuration. (col. 6, lns. 5-8.) The exterior wall engaging members 44 are then placed in a desired configuration by bending with the use of a forming tool, and they retain their bent configuration. (col. 6, lns. 8-14.) If the exterior wall engaging members 44 of *Kaster* were elastic, they would not maintain their bent configuration once the forming tool 11 was removed, but rather would return to the straight configuration of interior wall engaging members 43.

That exterior wall engaging members 44 are not elastic is also apparent from the manner in which staple 12 operates hold to form a vascular anastomosis. As described at col. 6, lns, 47-56 of *Kaster*, once interior wall engaging members 43

have pierced blood vessel 51, they are bent back upon themselves to firmly secure the blood vessel to the staple. Following the insertion of the staple/blood vessel through the side wall of another blood vessel, the exterior wall engaging members 44 are bent to engage the exterior wall of the second blood vessel. (col. 6, ln. 57 through col. 7, ln. 7.) Here again, if wall engaging members 44 exhibited elastic behavior, following removal of the stapling tool 10, they would return to the Fig. 10 configuration. Clearly, such action would defeat the entire purpose of staple 12 to hold the two blood vessels together.

Furthermore, when an element is *resiliently biased* to a position, it means that when the element is deflected away from that position, it will tend to return to that position once the deflecting force has been removed. From the discussion above, it will be clear that plastic materials in and of themselves cannot be resiliently biased to a position since, once the deflecting force has been removed, such materials would tend to remain in the deflected position. Only materials which exhibit some elastic behavior can be resiliently biased to return to their starting position.

While the stainless steel materials of *Kaster* may exhibit some degree of elastic behavior, it would only be for small amounts of deflecting force. Beyond such small amounts of force, the plastic behavior of these materials predominates. Certainly, the force required to deflect the wall engaging members of *Kaster* from a configuration extending "substantially radially out from the structure" to an orientation "substantially parallel to a central longitudinal axis of the structure" would far exceed the elastic range of behavior. Thus, the wall engaging members of *Kaster* would not be "elastically deflectable" to an orientation substantially parallel to the longitudinal axis of the structure, whereupon they would be "resiliently biased" to their original orientation

once the deflecting force has been removed.

Yencho plainly fails to overcome the deficiencies of *Kaster* discussed above. *Yencho* describes two different stents for attaching a graft to a blood vessel – a large vessel stent for use with large diameter target vessels such as the aorta, shown in Figs. 1-11, and a small vessel stent for use on target vessels having a small diameter such as a coronary artery, shown in Figs. 12-29. (*Yencho*, abstract.) Although *Yencho* describes that the small vessel stent may be formed from a superelastic or pseudoelastic material such as nitinol (col. 8, lns. 17-20), nothing in the reference suggests that the large vessel stent may be made from the same materials. Indeed, *Yencho* expressly states that the large vessel stent should be made from stainless steel, tantalum, titanium and alloys thereof. (col. 13, ln. 66 through col. 14, ln. 2.) In either case, nothing in *Yencho* suggests that either stent includes a plurality of first members *resiliently biased* to extend substantially radially out from the structure, and *elastically deflectable* to an orientation substantially parallel to the longitudinal axis of the device. That this is the case with the large vessel stents shown in Figs. 12-29 of *Yencho* is plainly evident from a review of how these stents operate.

As described at col. 10, ln. 11 through col. 11, ln. 24 of *Yencho*, stent 111 has deformable sections 115 and 116, each of which includes a plurality of helical members 123 and 124, respectively. Rotation of the proximal end of the stent body relative to the distal end of the stent body causes the helical members to deform outwardly as shown in Fig. 15. (col. 10, lns. 34-40.) The outwardly deformed sections define flanges 121 and 122 which engage the target vessel 127 and securely connect the graft vessel 125 thereto, all as shown in Fig. 20. If flanges 121 and 122 were resiliently biased to extend radially out from the structure, as shown in Fig. 20, one would

not have to rotate the ends of the stent relative to one another in order to form the flanges — they would assume this configuration automatically. Moreover, nothing in *Yencho* suggests that, if flanges 121 and 122 were elastically deflected to an orientation substantially parallel to the longitudinal axis of the stent, they would be resiliently biased to their orientation extending radially out from the stent once the deflecting force has been removed.

Hence, nothing in either of the references relied upon by the Examiner suggests a plurality of first members *resiliently biased* to extend substantially radially out from the structure and *elastically deflectable* to an orientation substantially parallel to a central longitudinal axis of the structure.

Moreover, contrary to the Examiner's assertion, applicants submit that one of ordinary skill in the art would have no reason to combine the "nitinol" teaching of *Yencho* with the staples of *Kaster*.

As noted above, the staple of *Kaster* operates by *plastic* deformation such that once it is bent to a particular configuration, it remains in that configuration to securely hold two blood vessels together. Forming the wall engaging members 43 and 44 of *Kaster* so they are elastic and resiliently deformable would obviate the entire insertion method taught by *Kaster*, including the use of the stapling tool 10, the staple forming tool 11 and the mandrel 16 for bending the members to their final configuration. Indeed, if the wall engaging members of *Kaster* were resiliently biased to their final configuration shown in Fig. 19, an entirely different method than that taught by *Kaster* would be required to insert the staple for joining two blood vessels together. Hence, one of skill in the art having knowledge of *Kaster* would have absolutely no motivation to form the wall engaging members so as to be resiliently biased to

extend substantially radially out from the structure.

Rather than finding the motivation to combine the references in the prior art, the Examiner's rejection is a classic example of hindsight reconstruction in which the Examiner has selected teachings from multiple prior art references to create the subject matter claimed by applicants using the applicants' specification as a "template." *Texas Instruments, Inc. v. U.S. Int'l. Trade Comm'n.*, 988 F.2d 1165, 26 U.S.P.Q. 2d 1018 (Fed. Cir. 1993). The impropriety of such hindsight reconstruction is well settled. *Interconnect Planning Corp. v. Feil*, 744 F.2d 1132, 227 U.S.P.Q. 523 (Fed. Cir. 1985); *In re Fine*, 837 F.2d 1071, 15 U.S.P.Q. 2d 1596 (Fed. Cir. 1998). Although the recent Supreme Court decision in *KSR Int'l. Co. v. Teleflex, Inc.*, 127 S.Ct. 1727 (2007), rejected a "rigid application" of the "teaching, suggestion or motivation" test for combining reference teachings, the decision reaffirms the principle that there still must be an apparent reason to combine elements taught by plural references. No such reason is apparent here.

In view of the foregoing, applicants submit that claim 83 patentably distinguishes over *Kaster* and *Yencho*, including any combination which the Examiner contends can be made therefrom.

In addition to the foregoing, applicants submit that there are several other bases upon which claim 83 distinguishes over the combination of *Kaster* and *Yencho*. In that regard, applicants would direct the Examiner's attention to the additional limitation in claim 83 for

> "a plurality of second members...being *resiliently biased* to extend substantially radially out from the structure and being *elastically deflectable* to an orientation substantially parallel to the central longitudinal axis of the structure."

(emphasis added)

For the same reasons as discussed above, applicants submit that neither *Kaster* nor *Yencho* teaches or suggests this feature.

Additionally, applicants would direct the Examiner's attention to the further requirement in claim 83 for

> "a plurality of closed shapes, each of which has an open center, and each of which is compressible and expandable in a *direction that is annular of the structure.*" (emphasis added)

The Examiner has acknowledged that *Kaster* fails to teach or suggest the foregoing feature, and has contended that *Yencho* overcomes this deficiency of *Kaster*. Applicants disagree.

Applicants acknowledge that *Yencho* teaches a connector having a plurality of closed shapes either between elements 123 and 124, as shown in Fig. 12, or closed shapes 129 in Fig. 21. However, applicants disagree that each of these shapes is compressible and expandable in a direction that is annular of the structure. More particularly, referring to Fig. 15, applicants submit that these shapes expand in an outward radial direction so as to form a larger circumference, but nothing in the reference suggests that these shapes expand or contract in the annular direction, *i.e.*, that members 123 or 124 move closer to one another in the annular direction. Indeed, since elements 123 are connected at their opposite ends to solid rings 111 and 113, and elements 124 are connected at their opposite ends to solid rings 111 and 112, applicants submit that these members simply cannot move closer to one another in the annular direction. Hence, this is another basis on which claim 83 distinguishes over the combination of *Kaster* and *Yencho*.

Still further, applicants would direct the Examiner's attention to the requirement in claim 83 that

> "each of the closed shapes being connected to a next adjacent closed shape in the row along *only* a central portion of a length of a side of the shape that is transverse to the direction, end portions of the length of the side that continue beyond either end of the central portion being spaced from the next adjacent closed shape in the direction that is annular of the structure so that expansion of any of the shapes in the direction that is annular of the structure causes the entirety of the structure and the entirety of the connector to annularly enlarge." (emphasis added)

The Examiner has acknowledged that *Kaster* also fails to teach or suggest these limitations of claim 83, but has contended that *Yencho* provides this missing teaching. Applicants respectfully disagree with the Examiner's position.

Initially, applicants note that the foregoing limitations of claim 83 require each of the closed shapes to be connected to a next adjacent closed shape along *only* a central portion of a length of a side of the shape that is transverse to the direction. The annotated reproduction of Fig. 21 of *Yencho* which the Examiner included in the Official Action clearly establishes the failure of *Yencho* to teach this requirement. That is, one of the Examiner's annotations points to two continuous strips of material which are labeled "end portions of central portion." As these strips of material are continuous, they plainly connect one central portion to the next. Thus, if one were to cut through what the Examiner labeled as the "sides of closed shapes transverse to annular direction," the closed shapes would still remain connected to one another. In contrast, if one were to cut through the sides of the closed shapes transverse to the length direction in applicant's device,

the closed shapes would separate entirely from one another since this is the *only* point where adjacent closed shapes are connected to one another.

Furthermore, the fact that the end portions of the central portion define continuous strips in the annular direction makes it clear that *Yencho* does not teach the requirement "end portions of the length of the side that continue beyond either end of the central portion being spaced from the next adjacent closed shape in the direction that is annular of the structure." The fact that the strips are continuous prevents the side of one closed shape from being spaced from the side of an adjacent closed shape. It is thus clear that *Yencho* fails to teach the foregoing requirements of claim 83 and, therefore, fails to overcome the deficiencies of *Kaster* acknowledged by the Examiner.

For all of the foregoing reasons, it is clear that claim 83 patentably distinguishes over both *Kaster* and *Yencho*, including their attempted combination.

Claims 84-87 and 89-90 depend either directly or indirectly from claim 83 and include all of the limitations of that claim. For at least this reason, applicants submit that these dependent claims also distinguish patentably over the combination of *Kaster* and *Yencho* such as to warrant their immediate allowance, which action is respectfully requested.

Finally, applicants note that newly inserted claim 100 includes several of the same limitations discussed above, none of which are taught by either *Kaster* or *Yencho*. For this reason, applicants submit that claim 100 patentably distinguishes over these references and its allowance is respectfully requested.

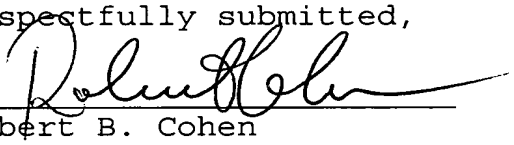
In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is

respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that she telephone applicants' attorney at (908) 654-5000 in order to overcome any additional objections which she might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

Dated: November 13, 2009

Respectfully submitted,

By 

Robert B. Cohen
Registration No.: 32,768
LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK, LLP
600 South Avenue West
Westfield, New Jersey 07090
(908) 654-5000
Attorney for Applicants

LD-446\

1096915_1.DOC